Date Received in Office: _____ HPRC #: _____

APPLICATION FOR FULL REVIEW

Date _____

Investigator(s) _____Phone_____E-mail_____

_____Phone_____E-mail_____

Research Staff_____Phone_____E-mail_____

Mailing Address_____

Project Title:_____

Check one of the following:

Faculty Research

Graduate Student Research
Advisors name _Phone

Undergraduate Student Research
Advisors name _Phone

Other (specify)

Anticipated dates of project: Beginning: Ending:

FUNDING: Anticipated source of funds, if any. (If this project will be funded under a grant to another investigator, please give the title of the grant, name of agency or institution, and the investigators name.)

Proposal has been /will be submitted for funding (date)

Will proposed research be conducted in team with investigator(s) from other agency/institution(s)? Yes _No

If yes, list agency/institution(s) and investigators

Is proposed research being conducted to meet course or degree requirements at another university? Yes No

If yes, has the research been reviewed by that university's IRB (Institutional Review Board)? Yes No

Results? (Attach Notification)

Is this research subject to review by another committee?
(check all that apply)

Radiation Safety Committee Biosafety Committee Research Integrity Committee
Intellectual Property Animal Care and Use Committee (TUIACUC) Chemical Hazards Committee

*It is the responsibility of the investigator to secure approval from these Committees and provide documentation for the HPRC.

Rev. 10/20/03

PARTICIPANT INFORMATION

Total number of Participants and Controls _____ ____Males ____Females

CATEGORIES OF PARTICIPANTS AND CONTROLS

- Adults (18 years and over)
- Adolescents (13-17 years of age)
- Mid-Childhood (6-12 years of age)
- Preschool (3-5 years of age)
- Infants (0-2 years of age)
- Pregnant Women
- Other (specify)
- Using existing data, no subjects recruited

INSTITUTIONAL AFFILIATION OFPARTICIPANTS

- None
- Schools/College/University
- Prisons
- Hospitals/Clinics
- Other (specify)

Mentally Competent (able to give consent) Mentally Incompetent (unable to give consent)

DEMOGRAPHIC DATA (Check all variables included)

- Names of Participants
- Addresses
- Phone numbers
- Age
- Sex
- Ethnicity
- Marital status
- Income
- Social Security Number
- Job Title
- Names of Employers
- Types of Employers
- Other Unique Information
- Specify

PARTICIPANT SELECTION:

a) How will the participants be chosen? (If using existing records, attach a copy of the permission.)

b) Provide rationale for using special populations (examples are: women, children, prisoners, pregnant women, mentaly disabled, economically or educationally disadvantaged persons. These groups are considered "vulnerable" or require consideration by the federal regulatory agencies and by the HPRC.)

c) How will the participants be recruited and contacted? (Suggestion: Attach a copy of advertisement or bulletin board notice and any recruitment letter or materials.)

d) Will the participants receive any compensation or inducement to participate either before or after the research? If yes, describe.

e) Cost to the participants:

1. What is the time requirement for the participants?

2. Will participants be charged for any research related procedures? If yes, explain.

Describe any potential short and long term benefits from this research to:

Participants:

Society (Science):

Study site: Where will the research be conducted?

If not at Tuskegee University, has permission been granted? (Attach a copy of letter of permission)

RESEARCH PROJECT DESCRIPTION

Use lay terms and/or provide definitions of technical terminology. [Use extra pages as necessary.]

1. Briefly describe the background or justification for your research.

2. Describe your research focus (the purpose or questions to be answered).

3. Describe the research design including the use of a control group and any intervention or treatment to be administered to the subjects whether performed by the researchers or others.

4. Describe your data collection procedures in detail.
   What will the participants (and controls) be doing to create the data (e.g., filling out a survey, performing a task, etc.)?
   If the participant will need training, explain in detail. (Attach copies of any instruments, tests, surveys, interview guides, etc. and descriptions of any research data collection equipment.)

RISKS TO PARTICIPANTS

Will the human participants be placed at risk of physical, psychological, social, legal, or other harm as a consequence of participating in this research? Check (3): yes or no. If yes, answer the questions directly below.

		YES	NO
1.	Possible invasion of privacy of participant or family, including use of personal information or records?		
2.	The administration of physical stimuli other than auditory and visual stimuli associated with normal situations and levels?		
3.	Deprivation of physical or psychological requirements such as nutrition or sleep; manipulation of psychological and/or social variables, e.g., sensory deprivation, social isolation, psychological stresses, etc.		
4.	Deception as part of the experimental procedure (if the study involves the use of deception, the protocol must include a description of this fact and the a debriefing procedure which will be used upon completion of this study).		
5.	Any probing for information which an individual might consider to be personal or sensitive (sexual or illegal activities, alcohol or drug use)?		
6.	The presentation to the subjects of any materials which they might find to be offensive, threatening, or degrading?		
7.	The requirement of physical exertion beyond normal situations?		

If any of the above items are checked YES, indicate:

(1) What precautions have been taken to minimize these risks?

(2) What arrangements have been made for the care of a participant in the event of an accident or complication related to the research?

NOTE: Add this statement to the consent form if more than minimal risk of physical harm: In the case of an emergency a participant may be seen at a local or regional medical facility. All expenses associated with care will be the responsibility of the participant and his/her insurance.

CONFIDENTIALITY OF DATA:

1. Will any data be made a part of any permanent record that can be identified with the participants? If yes, explain.

2. What steps will be taken to ensure the confidentiality of the data? (How will the participant's privacy be protected?)

3. Where will the data be stored for the three (3) year minimum? Specify the precise location, preferably in a locked file cabinet with limited access by others. Please explain how the data will be destroyed after the 3 year storage limit has been satified.

INFORMED CONSENT PROCEDURES

Review the consent/permission/assent templates

1. What type of informed consent will be used? (Check all that apply)

   _____Written consent agreement. (Attach a copy.)

   Implied consent - anonymous survey, etc. (Add this statement after the informed consent or cover letter: I understand that the return of this completed survey constitutes my informed consent to act as a participant in this research.)

   _____Oral consent. (Attach a copy of the script and the short written form.)

   _____Waiver from consent. (Justify the request for the waiver.)

2. Describe the process for obtaining consent/permission/assent from the participants, parents and/ legal guardians.

3. Is any information regarding the research being purposely withheld from the participants?

   _____Yes _____No

   If yes, provide the following information:

   a) state information purposely withheld from participants,

   b) justify the reason for this,

   c) describe the post-research debriefing of the participant, including when and where participants will be debriefed.

INVESTIGATOR AGREEMENT

I agree to follow the procedures outlined in this summary description and any attachments to ensure that the rights and welfare of human participants in my research are properly protected. I understand that no contact may be initiated with participants until I have received approval of these procedures from the Human Participant Review Committee (HPRC) and complied with any required modifications in connection with that approval.

I further understand that additions or changes in the procedures involving human participants or any adverse events or problems with the rights or welfare of the human participants must be promptly reported to the Office of Grantsmanship and Compliance.

I further understand that participant data and research records must be maintained in a secure and safe location for a period of at least three (3) years after research is completed. The original data will be provided to the HPRC if so requested.

Signature of Investigator Date

Signature of Investigator Date

Signature of Investigator Date

AFTER COMPLETING THESE FORMS, RETURN THE ORIGINAL AND ONE COPY OF ALL MATERIALS AND ATTACHED DOCUMENTS TO:

Office of Grantsmanship and Compliance
Tuskegee University
Chappie James Center
Tuskegee, AL 36088
Phone: 334-724-4223
Fax: 334-727-8801

*Full review - send the original and 1 copy (2 total).
*Expedited review - send the original and one (1) copy (2 total).

CONSENT AGREEMENT CHECK LIST
If NO is checked, explain why.

PLEASE ATTACH WITH APPLICATION

Elements of Informed Consent:

	YES	NO	NA
1. States the name and the title of the research project at the top of the consent agreement.			
2. Uses the term research.			
3. Investigators names, addresses and phone numbers given.			
4. Purpose of the Research: what will be assessed or studied.			
5. States how and why the participant is recruited and eligible to participate.			
6. If student research, how it relates to your program of study (thesis, class project, honors project, etc.).			
7. Explains Procedures in lay language; what the participants and controls will do, any training needed; time to complete, frequency; and the kind or type of information gathered.			
If audio/video taping, procedures clearly explained.			
8. Potential Risks, Discomforts and inconveniences are described.			
9. Potential Benefits of the Research to the participant, science and/or society are described.			
10. Confidentiality and Data Storage: explains how confidentiality and privacy will be preserved.			
Explains what will happen to the information, data and materials after the research is finished (storage, etc.).			
11. Participation and Withdrawal: voluntary participation; right to refuse to participate without penalty;			
right to withdraw, how to withdraw and who to contact.			
12. Questions about the Research: states participant may ask how and who to contact for additional questions later.			
13. Statement about review and approval by TU's HPRC.			
14. Participant's signature indicates their agreement to participate.			
15. Participant's returning a completed survey without signature indicates consent.			
16. Statement saying participant is to keep a copy of the full informed consent.			

Additional Elements of Informed Consent if Applicable

17. If participant is a minor then:			
a) Parent informed permission agreement and signature line;			
b) Child informed assent present			

18. Incentives to Participate: what is offered and how to get it.

19. Reasons for Exclusion from this Study for participant's safety.

21. In Case of Injury statement if more than minimal physical risk.

22. Informs participants if they are not being completely informed and that they will be informed after data collection.

APPLICATION CHECKLIST-DO NOT ATTACH WITH APPLICATION

This checklist is to help you verify the completeness of your research proposal application for HPRC review. Remember, if your application is not complete, it will be returned to you to complete and re-submit.

_____ Is the time frame for the research project given?

_____ Does the application state the purpose of the research?

_____ Does the application describe the participant (and control) population and the recruitment process?

_____ Are copies attached of participant recruitment flyers, advertisements, newspaper and/or e-mail announcements?

_____ Is the demographic information listed that will be collected about the participants?

Does the application summarize (in lay language) the procedures and tasks which the participants and/or controls will be asked to complete?

_____ Has the investigator made every possible provision for minimizing physical/mental/emotional/legal risks?

_____ Has the investigator described the procedures employed to preserve confidentiality/privacy?

_____ Has the investigator described the procedures used to obtain informed consent/permission/assent?

_____ If more than minimal risk of physical harm, has the "in case of injury" statement been added to the consent form?

_____ Is a copy included of the informed consent/permission/assent?

_____ Are copies attached of instruments, questionnaires, surveys, tests and supporting documents?

_____ Have provisions been made for maintaining data for at least 3 years?

_____ Is the location of data storage and who will have access to it stated in the application?

_____ Have all investigators signed the Investigator's Agreement?

CATEGORIES OF EXEMPTION FROM FURTHER HPRC REVIEW

The HPRC retains final judgment as to whether a research study is exempt from further HPRC review.

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from further HPRC review. The exempt status does not necessarily mean that the investigator is exempt from informed consent requirements. Please review the following information. If your research falls under one or more of these categories, fill out the exemption application forms only.

A. Research conducted in established or commonly accepted educational settings, involving normal education instruction practices, such as:
   1. research on regular and special education instruction strategies; or
   2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   1. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants;

   2. and any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (B) of this section, if:
   (1) the human participants are elected or appointed officials or candidates for public office; or
   (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

E. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

   (1) public benefit or service programs;
   (2) procedures for obtaining benefits or services under those programs;
   (3) possible changes in or alternatives to those programs or procedures; or
   (4) possible changes in methods or levels of payment for benefits or services under those programs.

F. Taste and food quality evaluation and consumer acceptance studies,

   (1) if wholesome foods without additives are consumed; or
   (2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Date Received in Office: _____ HPRC #: _____

APPLICATION FOR EXEMPTION

Exemption applies only to research with minimal risk. It does not apply to research involving prisoners, children or other vulnerable categories of subjects. Final determination as to whether a research project is exempt further review rests with the HPRC. If the project is determined to be exempt by the HPRC, the principal investigator is still required to submit any project modifications to the HPRC. The exempt status does not necessarily mean that the investigator is exempt from informed consent requirements.

Date _____

Investigator(s)_____

Address _____Phone _____

Project Title _____

Anticipated dates of project: Beginning: Ending:

FUNDING: Anticipated source of funds, if any. (If this project will be funded under a grant to another investigator, please give the title of the grant, name of agency or institution, and the investigators name.)

RESEARCH CATEGORIES OF EXEMPTION FROM FURTHER HPRC REVIEW

Research activities in which the only involvement of human subjects will be in one or more of the following categories are usually exempt from further HPRC review. Check all that apply to your research study.

A. Research conducted in established or commonly accepted educational settings, involving normal education instruction practices, such as
   (1) research on regular and special education instruction strategies, or
   (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (1) information obtained will be recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
   (2) any disclosure of the human participants responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants financial standing, employability, or reputation.

C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph B (2) of this section, if:
   (1) the human participants are elected or appointed officials or candidates for public office; or
   (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:
   (1) the sources are publicly available, or
   (2) the information will be recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

E. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
   (1) public benefit or service programs;
   (2) procedures for obtaining benefits or services under those programs;
   (3) possible changes in or alternatives to those programs or procedures; or
   (4) possible changes in methods or levels of payment for benefits or services under those programs.

F. Taste and food quality evaluation and consumer acceptance studies, if:
   (1) wholesome foods without additives are consumed or
   (2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: If you have checked B (1) and B (2) your research is not exempt from HPRC review. You must apply for full or expedited HPRC review.

RESEARCH PROJECT DESCRIPTION

Use lay terms and/or provide definitions of technical terminology. [Use extra pages as necessary.]

1. Briefly describe the background or justification for your research.

2. Describe your research focus (the purpose or questions to be answered).

3. Describe the research design including the use of a control group and any intervention or treatment to be administered to the subjects whether performed by the researchers or others.

4. Describe your data collection procedures in detail.
   What will the participants (and controls) be doing to create the data (e.g., filling out a survey, performing a task, etc.)?
   If the participant will need training, explain in detail. (Attach copies of any instruments, tests, surveys, interview guides, etc. and descriptions of any research data collection equipment.)

PARTICIPANT INFORMATION:

Complete the following information and include with application for EXEMPTION STATUS.
Use N/A rather than leaving a blank space.

Attachments: Please check all that apply

questionnaire/survey, script, etc. to be used with participants
consent agreement, cover letter/telephone introductory script or justification for waiver
permission to use existing data and/or permission from external institution (if applicable)

1. Subjects: Total # Age or age range:
2. Source of participants or existing data:
3. What is required of a participant:
4. Informed Consent ? ____NO ____YES (attach copy) ____Not Applicable
5. Will you retain any: Identifiers? ____NO ____YES Demographic data? ____NO ____YES (If yes, list)
6. How will confidentiality/privacy be maintained if identifiers are contained in the data?
7. Location of research (if not at T.U., obtain documented permission and attach copy):

An informed consent COVER LETTER (or telephone introduction script) addressed to the participants must accompany any survey or questionnaire. The cover letter or telephone script must include the following. If certain elements are left out, justify why this is necessary. See Template for Informed Consent Cover Letter.

a. A statement that the project is research being conducted for . . . (a paper or presentation or in partial fulfillment of the requirements for a course, thesis, independent study, etc.).
b. A comprehensive though succinct description of the study in narrative form.
c. A statement that participants' response will/will not be kept anonymous or confidential (explain extent of confidentiality if participants' names are requested).
d. If audio taping, a statement that the participant is being audio taped (explain how tapes will be stored or disposed of during and after the study).
e. A statement that participants do not have to answer every question.
f. If applicable, a statement that the participant's class standing, grades, or job status (or status on an athletic team) will not be affected by refusal to participate or by withdrawal from the study.
g. A statement that participation is voluntary.
h. A question directly asking the participant if he/she agrees to participate in the study

INVESTIGATOR AGREEMENT

I verify that risks to subjects are minimal. I agree to ensure that the rights and welfare of human subjects in my research are properly protected.

I understand that additions or changes in the procedures involving human subjects or any problems with the rights or welfare of the human subjects must be promptly reported to the HPRC administrator.

I further understand that subject data and research records must be maintained in a secure and safe location for a period of at least three (3) years after the research is completed. The original data will be provided to the HPRC if so requested.

Signature of Investigator Date

Signature of Investigator Date

AFTER COMPLETING THESE FORMS, RETURN THE ORIGINAL AND ONE (1) COPY OF ALL MATERIALS AND ATTACHED DOCUMENTS TO:

Office of Grantsmanship and Compliance
Tuskegee University
Chappie James Center
Tuskegee, AL 36088
Phone: 334-724-4223
Fax: 334-727-8801

The following pages contain temples for: informed consent agreement, informed consent cover letter, parental permission, informed assent. Please review the temples and choose the temple(s) that will be used for your project. Include a sample of informed consent form with your application to expedite HPRC review. If you need further assistance please contact the Office of Grantsmanship and Compliance at 334-724-4223.

INFORMED CONSENT TEMPLATE

Note: One of the most common reasons for delay of Human Participant Review Committee (HPRC) approval is an inadequate informed consent agreement. It is recommended that you follow this template, write in the 2nd person, use #12 font size and target a sixth to eighth grade reading level. Statements in bold type should be included verbatim; however they do not need to be in bold type in your consent agreement.

Informed Consent
(Your Research Study Title)

[If including the exact title might bias the results, use a general title instead.]

You are being asked to participate in a research study. Before you give your consent to volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Investigators
Provide the names and degrees of all investigators involved in the research study. Indicate the department and institution with which the investigator(s) is affiliated. If you are a student, include the name of your faculty advisor. Also provide the HPRC addresses and phone numbers.

Purpose of the Research
This research study is designed to . . . (state what the study is designed to assess or study).
The data from this research will be used to . . . (explain how data will be used).
If you are a student, indicate how the results will contribute to your course of study.

Procedures
If you volunteer to participate in this study, you will be asked to . . . [describe what subject will do using lay language].
[If controls are used, also explain what will be expected of the controls.]
(If the description is complicated, bulleting or listing works well.)
Your participation will take approximately . . . [estimate amount of times, frequency etc.].
If standard treatment will be withheld, state this here.
If any procedures are experimental, identify them here.

Potential Risks or Discomforts
DO NOT state that there are no risks or discomforts. You may say there are no foreseeable risks associated with the study.
Describe any reasonable foreseeable risks, discomforts, inconveniences, or costs associated with this research that the participants may encounter. These could be physical, psychological, emotional, social or economic. Inform the participant of any provisions for managing these and of the subject's right to discontinue participation, either temporarily or permanently.

Potential Benefits of the Research
Describe any benefits the participants can expect as a result of participating in the study. If there are no benefits to the participants, state this. Describe any potential benefits to science and society that may result from this research.

Confidentiality and Data Storage
Describe the precautions that will be taken to preserve the confidentiality/privacy of participants. If confidentiality will not be maintained, state this and explain if names, images or tapes will be used and how and when they will be used.
Include the procedures for using and storing data (e.g., in Dr. X=s office) and include who will have access to the data (e.g., the investigator and advisor). (It must be stored at TU for at least 3 years after completion of the study.)
If video or audio tapes will be used to record information, describe exactly how the recordings will be used, who will have access, how long the recordings will be stored and when they will be destroyed.

Participation and Withdrawal

Your participation in this research study is voluntary. As a participant you may refuse to participate at anytime. If you decide to participate, you are free to withdraw at anytime. To withdraw from the study please contact the. . .(explain how to withdraw, whom to contact). Note: if the data are anonymous, subjects cannot withdraw after data collection has taken place.

Questions about the Research

If you have any questions about the research, please speak with (state whom to contact). If you have questions later, you may contact . . . (state whom to contact,).

This project has been reviewed and approved by the Human Participant Review Committee for the Protection of Human Participants at Tuskegee University. If you believe there is any infringement upon your rights as a research participant, you may contact the HPRC Chair, Dr. Stephen Sodeke at 334-724-8210.

You have been given the opportunity to ask questions and these have been answered to my satisfaction. My signature below indicates my voluntary agreement to participate in this research study.

Please return one copy of this consent form and keep one copy for your records.
[If audio/video taping and/or names will be used, add a statement about also agreeing to be taped and/or named.]

Signature of Research Participant Date

Participant Name (Please Print) Date

Signature of Person Obtaining Consent (optional) Date

ADDITIONAL ELEMENTS ONLY WHEN APPROPRIATE

Incentives to Participate

If an incentive is offered, describe what is being offered and what is required to obtain the incentive.

Reasons for Exclusion from this Study

State in basic lay language reasons why a subject should be excluded from participating (e.g., being a smoker, pregnant, under the age of 18, a medical condition). Include only those reasons which could not be pre-determined by the investigator.

In Case of Injury [Include this section if your study involves more than minimal risk.]

It is unlikely that participation in this project will result in harm to participants. If an injury to a participant does occur, he or she may be seen at a local or regional medical facility. All expenses associated with care will be the responsibility of the participant and his/her insurance. (If the research is not conducted at T.U., leave out the option of using local or regional medical facility.)

INFORMED CONSENT COVER LETTER TEMPLATE
(No signature required of participant, usually used with anonymous surveys.)

Note: One of the most common reasons for delay of HPRC approval is an inadequate informed consent. It is recommended that you follow this template, write in the 2nd person, use #12 font size and target a sixth to eighth grade reading level. Statements in bold type should be included verbatim; however they do not need to be in bold type in your consent agreement.

Informed Consent Cover Letter
(Research study title)

[If including the exact title might bias the results, use a general title instead.]

You are being asked to participate in a research study. Before you give your consent to volunteer, it is important that you read the following information to be sure you understand what you will be asked to do.

Investigators
Provide the names and degrees of all investigators involved in the research study. Indicate the department and institution with which the investigator(s) is affiliated. If you are a student, include the name of your faculty advisor. Also provide the TU addresses and phone numbers.

Purpose of the Research
This research study is designed to . . . (state what the study is designed to assess or study).
The data from this research will be used to . . . (explain how data will be used).
If you are a student, indicate how the results will contribute to your course of study.

Procedures
If you volunteer to participate in this study, you will be asked to . . . [describe what subject will do using lay language].
[If controls are used, also explain what will be expected of the controls.]
(If the description is complicated, bulleting or listing works well.)
Your participation will take approximately . . . [estimate amount of times, frequency etc.].
If any procedures are experimental, identify them here.

Potential Risks or Discomforts
DO NOT state that there are no risks or discomforts. You may say there are no foreseeable risks associated with the study.
Describe any reasonable foreseeable risks, discomforts, inconveniences, or costs associated with this research that the participants may encounter. These could be physical, psychological, emotional, social or economic. Inform the participant of any provisions for managing these and of the subjects right to discontinue participation, either temporarily or permanently.

Potential Benefits of the Research
Describe any benefits the participants can expect as a result of participating in the study. If there are no benefits to the participants, state this. Describe any potential benefits to science and/or society that may result from this research.

Confidentiality and Data Storage
Describe the precautions that will be taken to preserve the confidentiality/privacy of subjects (e.g., anonymous survey).
Include the procedures for using and storing data (e.g., in Dr. X=s office) and include who will have access to the data (e.g., the investigator and advisor). (It must be stored at TU for at least 3 years after completion of the study.)
If video or audio tapes will be used to record information, describe exactly how the recordings will be used, who will have access, how long the recordings will be stored and when they will be destroyed.

Participation and Withdrawal
Your participation in this research study is voluntary. As a participant you may refuse to participate or stop at anytime. To stop. . . (tell how, e.g., simply stop answering the questions).

Questions about the Research
If you have any questions about the research, you may contact . . . [name phone].

This project has been reviewed by the Human Participant Review Committee for Tuskegee University. If you believe there is any infringement upon your rights as a research participant, you may contact the HPRC Chair, Dr. Stephen Sodeke at 334-724-8210.

You have been given the opportunity to ask questions and these have been answered to my satisfaction. By returning a completed questionnaire/survey or by agreeing to be interviewed, etc…You are agreeing to participate in this research study.

KEEP THIS INFORMED CONSENT COVER LETTER FOR YOUR RECORDS.

Signature of Investigator Date

PARENTAL PERMISSION TEMPLATE

Note: One of the most common reasons for delay of HPRC approval is an inadequate informed consent agreement. It is recommended that you follow this template, write in the 2nd person, use #12 font size and target a sixth to eighth grade reading level. Statements in bold type should be included verbatim; however they do not need to be in bold type in your consent agreement.

Parent or Legal Guardian Permission for Child to Participate in a Research Study
[Research study title]

You are being asked to give permission for your child to participate in a research study. Before you give permission for your child to participate, it is important that you read the following information and ask as many questions as necessary to be sure you understand what your child is being asked to do.

Investigators

Provide the name and degrees of all investigators involved in the research study. Indicate the department and institution with which the investigator(s) is affiliated. If you are a student, include the name of your faculty advisor. Also provide the Tuskegee University addresses and phone numbers.

Purpose of the Research

This research study is designed to . . .[state what the study is designed to assess or study].
The data from this research will be used to . . . [explain how data will be used].
If you are a student, indicate how the results will contribute to your course of study.

Procedures

If you allow your child to participate in this study, he/she will be asked to . . . (describe what participant will do using lay language).
His/her participation will take approximately . . . (estimate amount of times, frequency etc.).
Your child will be asked to assent to participate in this research. He/she can refuse to participate without any penalty or can stop participation at any time just by telling the investigator that he/she wants to stop.
[If there will be a token gift for participation, mention it here.]
[If standard treatment will be withheld, state this here.]
[Identify any procedures that are experimental here.]

Potential Risks or Discomforts

DO NOT state that there are no risks or discomforts. You may say there are no foreseeable risks associated with the study.
Describe any reasonable foreseeable risks, discomforts, inconveniences, or costs associated with this research that the participants may encounter. These could be physical, psychological, emotional, social or economic. Inform the parents/legal guardians of any provisions for managing these and of the participants right to discontinue participation, either temporarily or permanently.

Potential Benefits of the Research

Describe any benefits the participant can expect as a result of participating in the study. If there are no benefits to the participants, state this. Describe potential benefits to science and society that may result from this research.

Confidentiality and Data Storage

Describe the precautions that will be taken to preserve the confidentiality/privacy of participants. If confidentiality will not be maintained, state this and explain if names, etc., will be used and how and when.
Include the procedures for using and storing data (e.g., in Dr. X=s office) and include who will have access to the data (e.g., the investigator and advisor). [It must be stored at TU for at least 3 years after completion of the study.]
If video or audio tapes will be used to record information, describe how the recording will be used, who will have access, how long the recording will be stored and when it will be destroyed.

Participation and Withdrawal

Participation in this research study is voluntary. You may refuse to allow your child to participate. If you decide to allow your child to participate, you are free to withdraw him/her at any time. To withdraw your child from the study. . . (explain how to withdraw, who to contact, phone, address, etc.). Note: if the data is anonymous, participants cannot withdraw after data collection has taken place.

Questions about the Research
If you have any questions about this research you may contact . . . [name, phone].

This project has been reviewed and approved by the Human Participant Review Committee at Tuskegee University. If you believe there is any infringement upon your child's rights as a research participant, you may contact the HPRC Chair, Dr. Stephen Sodeke at 334-724-8210.

Parent or Legal Guardian Permission:
You have read the information provided above. You have been given the opportunity to ask questions and these have been answered to my satisfaction. My signature below indicates that my child may participate in this research study. My child's assent to participate in this study will be sought.

Please return one copy of this consent form and keep one copy for your records.
[If audio/video taping and/or names will be used, add a statement about also agreeing to be taped and/or named.]

Name of Child (please print)

Signature of Parent/Legal Guardian Date

Name of Parent/Legal Guardian (please print) Date

Signature of Person Obtaining Permission Date

ADDITIONAL ELEMENTS ONLY WHEN APPROPRIATE

Incentives to Participate
If an incentive is offered, describe what is being offered and what is required to obtain the incentive.

Reasons for Exclusion from this Study
State in basic lay language reasons why a participant should be excluded from participating (e.g., a medical condition). Include only those reasons which could not be pre-determined by the investigator.

In Case of Injury (Include this section if your study involves more than minimal risk)
It is unlikely that participation in this project will result in harm to participants. If an injury to a participant does occur, he or she may be seen by a local or regional medical facility. All expenses associated with care will be the responsibility of the participant and his/her insurance.

INFORMED ASSENT TEMPLATE
(May or may not require signature of minor subject.)

Note: If children will be included in the study, an assent agreement is necessary. Age appropriate language should be used. A typical teenager could receive an assent (or an informed cover letter) using the same language as for an adult. If the child is not able to read, present this information verbally to obtain verbal assent. Attach the script of verbal assent to your application. Do not use the same form for parental permission and child assent.

Informed Assent
(Research study title)

Investigators at Tuskegee University are doing a project about . . . . This is called a research study.

The purpose of this research study is . . . [simple explanation of what you are trying to find out]

You are asked to be in this research study because . . . [simple explanation why the child is invited to participate]

The investigators (or people) in charge of this study are . . . [name the investigators]

This study will take place . . . [name study site] and will last . . . [indicate duration of child's participation]

During this study, this is what will happen: [simple explanation of procedures: lists often work well]

Mention any risks, discomforts and potential benefits of the study appropriate for the age level.

Use something like the following statement if confidential questionnaires are involved:
Only the investigator(s) doing this study will know your answers. Your parents [and teachers if study is conducted at child's school] will not know.

If appropriate, use one of the following:
You will not be given anything for being in this research study.
You will be given _____ for being in this research study.

Your Mom or Dad (or parents or Guardians) have said that it is okay for you to be in this research study. You do not have to be in this study if you do not want to. You can change your mind at any time by telling _____.

Please mark one of the choices below. [In using verbal assent, mere failure to object should not be construed as assent.]

KEEP A COPY OF THIS ASSENT FORM FOR YOURSELF.

_____NO, I do not want to be in this study. _____YES, I want to be in this study.

Name or Signature of Participant (Optional) Date
[Not used with anonymous surveys, etc.]

Signature of Person Obtaining Assent (Optional) Date

ADVERSE EVENT REPORT

If an adverse event or accident occurs to a participant during research, this report should arrive in the Office of Grantsmanship and Compliance within 24 hours of the event. Deliver the completed form to: Office of Grantsmanship and Compliance, Chappie James Center, Tuskegee, AL 36088. Phone No. 334-724-4223. Fax: 334-727-8801.

Date _____ HPRC#_____

Investigator(s)_____

HPRC Proposal Title:_____

Date and Place of Event:_____

Did the event result in medical treatment? ____ No ____Yes If yes, where? _____

Give a description of the adverse event as determined by the investigator. (Use back of form if more space is needed.)

Any follow-up action taken:

Individual Reporting Event:

Signature Date

Principal Investigator (and or Advisor):

Signature Date

HPRC Use Only

_Continue study as submitted and approved by HPRC
_Changes recommended
Report to Institutional Officials: (Date) / /
_Discuss with Principal Investigator

HPRC Chairperson Date

HPRC Administrator Date

Owner
D:20130723093025-05'00'7/23/2013 8:30:25 AM

Accepted set by Owner

FINAL REPORT FOR STUDENT RESEARCH

As soon as you have completed your research project, complete this form and return it to: Office of Grantsmanship and Compliance, Chappie James Center, Tuskegee, AL 36088

Student Investigator(s):_____

Faculty Advisor:

Project Title:

T.U. HPRC #: Department: College:

Reason for research project (check one): Undergraduate thesis _Graduate thesis

Class Assignment _Independent Study Other (name)

Date Research Started: Date Completed or Stopped:

If the research project was not completed as planned, please explain:

Did you receive: Outside financial support (e.g., grant money)? YES or NO

If YES to outside support, name the funding source:_____

PARTICIPANT INFORMATION

Total number of participants that participated: _____

Ages: _____18 yrs. or older, _____13-17 years, _____6-12 years, _____5 yrs. and under.

Any in protected categories? YES or NO If Yes, list: _____

PARTICIPANT ADVERSE EVENTS and/or COMPLICATIONS

Did any participant suffer an unanticipated or adverse event? YES or NO
If yes, explain on separate sheet and attach.

MODIFICATIONS TO PROJECT

Were any changes made to the project since original approval (e.g., changes in the consent process, investigators and/or protocol amendments)? YES or NO If yes, attach updated materials to this form.

I understand that I received HPRC approval for this project and time-frame only. If I want to continue this project or a new project I must receive HPRC approval again.

Signature of Student Investigator OR Faculty Advisor Date

FINAL REPORT for HUMAN PARTICIPANT RESEARCH

As soon as you have completed your research project, complete this form and return it to: Office of Grantsmanship and Compliance, Chappie James Center, Tuskegee, AL 36088

Investigator(s):_____

Project Title:

T.U. HPRC Approval Date: Department: College:

Date Research Started: Date Completed or Stopped:

If the research project was not completed as planned, please explain:

Did you receive: Financial support (e.g., grant money)? Please circle YES or NO

If YES to Financial support, name the funding source:_____

PARTICIPANT INFORMATION

Number of participants that participated: Male _____ Female_____Total_____

Total Number of Participant's for the ages of: 18 yrs. or older, _13-17 years, 6-12 years, 5 yrs. and under.

Any in protected categories? YES or NO If Yes, list: _____

PARTICIPANT ADVERSE EVENTS and/or COMPLICATIONS

Did any participant suffer an unanticipated or adverse event? YES or NO
If yes, explain on separate sheet and attach.

MODIFICATIONS TO PROJECT

Were any changes made to the project since original approval (e.g., changes in the consent process, investigators and/or protocol amendments)? YES or NO If yes, please attach updated materials to this form.

I understand that I received HPRC approval for this project and time-frame only. If I want to continue this project or a new project I must receive HPRC approval again.

Signature of Investigator Date